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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,146	09/16/2002	Wilhelm Amberg	51748	9829

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WOOD, PHILLIPS, KATZ, CLARK & MORTIMER
500 W. MADISON STREET
SUITE 3800
CHICAGO, IL 60661

EXAMINER

HADDAD, MAHER M

ART UNIT	PAPER NUMBER
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1644

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/089,146

Applicant(s)

AMBERG ET AL.

Examiner

Maher M. Haddad

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 7-10 is/are pending in the application.
- 4a) Of the above claim(s) 1-3 and 7-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 10/30/06, is acknowledged.
2. Claims 1-4 and 7-10 are pending.
3. Claims 1-3 and 7-9 stand withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention.
4. Claims 4 and 10 are under examination as they read on an a pharmaceutical composition for the treatment or prevention of cardiovascular diseases comprising an ET_A endothelin blocker and an α v β 3 integrin receptor antagonist and a trade package thereof.
5. In view of the amendment filed on 10/30/06, only the following rejections are remained.
6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claim 4 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Kirchengast *et al* (provided in the International Report and cited on the PTO-892 as reference Y) in view of Srivatsa *et al* (provided in the International Report and cited on the PTO-892 as reference W) for the same reasons set forth in the previous Office Actions mailed 7/26/06.

Applicant's arguments, filed 10/30/06, have been fully considered, but have not been found convincing.

Applicant alleges in conjunction with case laws that the Office Action has not pointed to any suggestion or motivation for one skilled in the art to modify kirchengast *et al* nor has the Examiner presented any line of argument as to why one skilled in the art would be motivated to combine an ET_A endothelin blocker and an α v β 3 integrin receptor antagonist. Further, Applicant contends that neither Kirchengast *et al* nor Srivatsa *et al* teach or suggest all the claim

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limitations. Kirchengast et al is directed to the use of ET receptor antagonists in restenosis. Nowhere does Kirchengast et al teach or suggest combining ET_A endothelin blocker and an α v β 3 integrin receptor antagonist. Srivasta et al is directed to α v β 3 integrin blockade limiting neointimal hyperplasia and lumen stenosis following deep coronary arterial stent injury. Applicant contends that the prior art fails to suggest the claimed invention and any reconstruction of the prior art to obtain that invention necessarily and inevitably requires impermissible hindsight. Applicant submits that the Office Action relies upon the teachings of the instant application rather than what is actually motivated by the prior art. Applicant submits that this is a telltale sign that hindsight has been used to formulate the obviousness rejection. Another sign is that the cited prior art references, even if taken together, do not result in the invention of claim 4. Applicant criticizes the Examiner use of the 2006/0089374 evidentiary reference as it was filed more than three years after the present application. Applicant concludes that the evidentiary reference does not reflect state of the art at the time the instant invention was made.

Again, the suggestion to combine each of the two components of the claimed composition is conventionally employed in the art for treating restenosis come within the purview of combining two or more materials where each is taught by the prior art to be useful for the same purpose. It would have been *prima facie* obvious, within the meaning of 35 U.S.C. 103 to employ these components in combination for their known functions and to optimize the amount of each additive. "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). See MPEP 2144.06.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). See MPEP 2145.

Regarding the post dated evidentiary reference 2006/0089374, it appears that Applicant does not dispute that facts presented in the reference put contends that the age of the reference does not reflect the state of the art at the time the invention was made. First, it is noted the 2006/0089374 is only evidentiary reference and is not part of the rejection. Second, the evidentiary references need not to have an early dated of the claimed invention but can be post dated references.

8. Claim 10 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Kirchengast *et al* (provided in the International Report and cited on the PTO-892 as reference Y) in view of Srivatsa *et al* (provided in the International Report and cited on the PTO-892 as reference W) as applied to claims 4-6 above, and further in view of US Pat. No. 4,761,406 for the same reasons set forth in the previous Office Actions mailed 7/26/06.

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Applicant's arguments, filed 10/30/06, have been fully considered, but have not been found convincing.

Applicant traverses the rejection base on the same reasons set forth above.

The Examiner's position is the same as set forth above.

9. No claim is allowed.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

January 14, 2007

Maher Haddad

Maher Haddad, Ph.D.
Primary Examiner
Technology Center 1600